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TO : EXAMINER MICHELE FLOOD, ART UNIT: 1654

COMPANY : UNITED STATES PATENT AND TRADEMARK OFFICE

FAX NO. : 703-872-9307

FROM : ALBERT WAI-KIT CHAN

DOCKET : SHEN, ET AL., FOR COMPOSITION COMPRISING
EXTRACTS OF FLOS LONICERAE, FRUCTUS
FORSYTHIZE AND RADIX SCUTELIARIAE, USES AND
PREPARATION THEREOF, U.S. SERIAL NO. 10/032,514,
FILED OCTOBER 24, 2001, CLAIMING PRIORITY OF
CHINESE PATENT APPLICATION NO. 00125764.1, FILED
ON OCTOBER 25, 2000 - DKT. #735-US

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TOTAL NUMBER OF PAGES, INCLUDING COVER SHEET : 12

DATE : January 6, 2004

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Message

Applicants: SHEN, et al.
Client: National Engineering Research Center for Traditional Chinese Medicine
File No.: 735-US
Date: January 6, 2003

COMMUNICATION TO SUBMIT THE SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENTS for SHEN, et al. for COMPOSITION COMPRISING EXTRACTS OF FLOS LONICERAE, FRUCTUS FORSYTHIZE AND RADIX SCUTELIARIAE, USES AND PREPARATION THEREOF, U.S. Serial No. 10/032,514, Filed October 24, 2001, claiming priority of Chinese Patent Application No. 00125764.1, filed on October 25, 2000.

THE INFORMATION CONTAINED IN THIS FACSIMILE TRANSMISSION IS INTENDED SOLELY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE DESIGNATED RECIPIENT(S) NAMED ABOVE. THIS TRANSMISSION MAY CONTAIN INFORMATION THAT IS CONFIDENTIAL UNDER THE CLIENT AND ATTORNEY RELATIONSHIP. IF THE READER OF THIS MESSAGE IS NOT A DESIGNATED RECIPIENT OR AN AGENT RESPONSIBLE FOR DELIVERING IT TO A DESIGNATED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT YOU HAVE RECEIVED THIS DOCUMENT IN ERROR, AND THAT ANY REVIEW, DISTRIBUTION, OR COPYING OF THIS MESSAGE IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, OR IF UPON READING THIS DOCUMENT YOU HAVE REASON TO BELIEVE THAT THE DOCUMENT WAS INADVERTENTLY SENT TO YOU, PLEASE NOTIFY US IMMEDIATELY BY COLLECT TELEPHONE CALL AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL. THANK YOU.

TO: P.002
JAN 06 2004
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Dkt. #735-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : SHEN, et al.
U.S. Serial No.: 10/032,514 Examiner: Michele Flood
Filed : October 24, 2001 Art Unit: 1654
For : COMPOSITION COMPRISING EXTRACTS OF FLOS
LONICERAE, FRUCTUS FORSYTHIAE AND RADIX
SCUTELLARIAE, USES AND PREPARATION THEREOF

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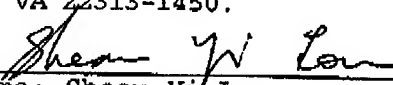
January 6, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

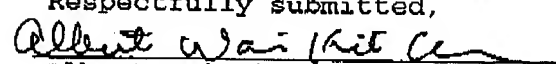
Sir/Madam:

FACSIMILE CERTIFICATE
IN CONNECTION WITH THE ABOVE-IDENTIFIED APPLICATION

I hereby certify that this paper is being sent on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Printed Name: Sheau Yi Lou

Respectfully submitted,


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World Plaza, Suite 604
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January 6, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants would like to direct the Examiner's attention to the following reference which is listed on Form PTO/SB/08B (Exhibit A) and is attached hereto as Exhibit 1.

1. The 02 January 2004 PCT Notification of Transmittal of International Preliminary Examination Report issued from International Preliminary Examining Authority.

Applicants : SHEN, et al.
U.S. Serial No.: 10/032,514
Filed : October 24, 2001
Page : 2

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai Kit Chan

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Exhibit A

Exhibit 1

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
ALBERT WAI-KIT CHAN
LAW OFFICES OF ALBERT WAI-KIT CHAN, LLC
WORLD PLAZA SUITE 604
141-07 20TH AVENUE
WHITESTONE, NY 11357

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

02 JAN 2004

Applicant's or agent's file reference

1053-A-PCT

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US01/50424

24 October 2001 (24.10.2001)

25 October 2000 (25.10.2000)

Applicant

NATIONAL ENGINEERING RESEARCH CENTER FOR TRADITIONAL CHINESE MEDICINE

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703)305-3230

Form PCT/IPEA/416 (July 1992)

Authorized officer

Christopher R. Tate

Telephone No. 703-308-0196

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1053-A-PCT		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US01/50424	International filing date (day/month/year) 24 October 2001 (24.10.2001)	Priority date (day/month/year) 25 October 2000 (25.10.2000)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 35/78 and US Cl.: 424/725, 741, 773, 777, 778			
Applicant NATIONAL ENGINEERING RESEARCH CENTER FOR TRADITIONAL CHINESE MEDICINE			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>A</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 24 May 2002 (24.05.2002)		Date of completion of this report 16 December 2003 (16.12.2003)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230		Authorized officer Christopher R. Tate Telephone No. 703-308-0196	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US01/50424

1. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
 pages 1-93 as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____
- ☒ the claims:
 pages 94-104 as originally filed
 pages NONE as amended (together with any statement) under Article 19
 pages NONE filed with the demand
 pages NONE filed with the letter of _____
- ☒ the drawings:
 pages 1-7 as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages NONE as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

Form PCT/IPEA/409 (Box I) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US01/50424

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 4-8 and 15-24

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 4-8 and 15-24

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Form PCT/IPEA/409 (Box III) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US01/50424**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>9-14, 25, 26, and 29</u>	YES
	Claims <u>1-3, 25, 27, 28, and 30-32</u>	NO
Inventive Step (IS)	Claims <u>12 and 13</u>	YES
	Claims <u>1-3, 9-11, 14, 25-32</u>	NO
Industrial Applicability (IA)	Claims <u>1-3, 9-14, and 25-32</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-3, 25, 27, 28, and 30-32 lack novelty under PCT Article 33(2) as being anticipated by Xu.

Xu teaches antibacterial, antiviral pharmaceutical compositions comprising Flos Lonicerae, Fructus Forsythiae, and Radix Scutellariae within the claimed amounts/ratios (see entire document).

Claims 1, 2, and 30-32 lack novelty under PCT Article 33(2) as being anticipated by Li.

Li teaches an antibacterial, antiviral pharmaceutical composition comprising Flos Lonicerae, Fructus Forsythiae, and Radix Scutellariae (see abstract).

Claims 1-3, 9-11, 14, and 25-32 lack inventive step under PCT Article 33(3) as being obvious over Xu and Li in view of Moyler.

Xu and Li teach antibacterial, antiviral pharmaceutical compositions comprising Flos Lonicerae, Fructus Forsythiae, and Radix Scutellariae. Xu further teaches these herbal agents within the claimed amounts/ratios (as discussed above).

Moyler beneficially teaches that supercritical CO₂ fluid extraction, including in conjunction with an alcoholic entrainer, is an effective and environmentally friendly method of preparing herbal plant extracts from various parts of plants (for example, fruits, roots, buds, etc.) - see entire document.

It would have been obvious to utilize supercritical CO₂ fluid extraction to efficiently (and without harming the environment) prepare the antibacterial, antiviral plant extracts taught by Xu and Li based upon the beneficial teachings provided by Moyler. The result-effective adjustment of conventional working parameters (for example: pressure, temperature, and/or time used during such CO₂ supercritical fluid extraction) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 12 and 13 meet the criteria under PCT Article 33(2)-(3), because the prior art does not teach nor reasonably suggest a method for preparing the claimed herbal agents via further including the step of embedding the supercritical extract with a saturated solution of beta-cyclodextrin as claimed.

Claims 1-3, 9-14, and 25-32 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter can be made or used in industry.

----- NEW CITATIONS -----

Form PCT/IPEA/409 (Box V) (July 1998)